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Applicants	:	John H. HEALEY and Gene R. DIRESTA
U.S. Serial No.	:	09/890,116
Filed	:	November 20, 2001
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REMARKS

By this Amendment, Applicants have amended claims 77, 93 and 110-115. Accordingly, there is no issue of new matter and Applicants respectfully request the entry of this Amendment. Upon entry, claims 77-115, 117, and 122-125 are pending and under examination.

Attorney Docket Number

Applicants respectfully request the Commissioner to change the Attorney Docket Number to: **850-PCT-US**

Telephone Interview with Examiner on April 3, 2006

A telephone interview was conducted with Examiner Jagoe on April 3, 2006. During the telephone interview the following items were discussed:

1. The rejection of claims 77-117 and 122-125 in the February 21, 2006 non-final Office Action based upon Merck WO 96/39107 and Sabokbar et al., *Ann Rheum Dis* 1998; 57:614-618 (October), specifically that a product in a product by process claim must be novel under MPEP § 2113.
2. The following were suggested: filing a continuation and focusing on "process of making" claims instead of composition claims; narrowing the composition claim by adding further limitations; and/or providing side-by-side experimental data and a § 1.132 Affidavit to distinguish the claimed subject matter from Merck.

In response, Applicants maintain that the amended claims provide different components which are distinguishable from

the cited art. Applicants believe that the amended claims should not raise the issues noted by the Examiner.

Claim rejection under 35 U.S.C. §102/103(a)

The Examiner rejected claims 77-117 and 122-125 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over WO 96/39107 (**Merck Co.**) and **Sabokbar et al.** (Ann. Rheum. Dis. 57:618 (1998)).

The Examiner contends that **Sabokbar et al.** teach that incorporation of a bisphosphonate into bone cement to inhibit macrophage-osteoclast differentiation may effectively be used to control periprosthetic osteolysis, and bisphosphonates included in bone cement may also be used to prevent or to control bone resorption seen in aseptic loosening.

The Examiner also contends that **Merck Co.** teaches the addition of further bisphosphonates to the cement, and the amount of bisphosphonate is generally from 0.005 to 10 percent of the total cement composition. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time it was made to add additional bisphosphonates as cited in **Merck Co.** as motivated by the reasoned expectation of producing a bone cement/bisphosphonate composition which is effective in comprehensively preventing formation of osteoclasts and loosening of prosthetic implants. Applicants respectfully traverse.

In response, Applicants submit that claims 77, 93, and 110-115 have been amended to recite the following limitations:

> a mixture comprising an anti-resorptive agent having a particle-size distribution which is about the same or less than that of a polymeric bone-cement component to provide for even distribution of the anti-resorptive

particles throughout a polymerized bone-cement matrix after polymerization reaction,

wherein the anti-resorptive agent is present in an amount that does not compromise the bone cement's chemical or mechanical properties

In contrast, **Sabokbar et al.** and **Merck Co.** do not teach or suggest a mixture comprising an anti-resorptive agent having a particle-size distribution which is about the same or less than that of a polymeric bone-cement component to provide for even distribution of the anti-resorptive particles throughout a polymerized bone-cement matrix as claimed herein. The Examiner has not provided any evidence that indicates **Sabokbar et al.** or **Merck Co.** teach or suggest such limitation.

Moreover, **Sabokbar et al.** and **Merck Co.** do not teach or suggest the anti-resorptive agent is present in an amount that does not compromise the bone cement's chemical or mechanical properties as claimed herein. The present specification teaches that one advantage of the present composition is that satisfactory biomechanical characteristics are maintained after incorporation of anti-resorptive agent (page 37, lines 7-13). As shown in Exhibit 1 presented herein, the bone cement composition of the present invention (MSKCC) exhibits the same mechanical strength as compared to bone cement without any addition of anti-resorptive agent (drug free SIMPLEX™). In contrast, the composition of **Merck Co.** has significantly decreased mechanical strength as compared to bone cement that does not contain anti-resorptive agent. Hence, the addition of anti-resorptive agent according to **Merck Co.** actually compromises the performance of the bone cement. The Examiner has not provided any evidence that indicates **Sabokbar et al.**

or **Merck Co.** teach or suggest addition of anti-resorptive agent would not compromise the bone cement's chemical or mechanical properties as claimed herein.

In summary, **Sabokbar et al.** or **Merck Co.** fails to teach or suggest each and every aspect of the present invention. Specifically, neither **Sabokbar et al.** nor **Merck Co.** teaches or suggests the two limitations listed above. In order to anticipate or render the present invention obvious, a reference(s) must teach each and every aspect of the present invention. Accordingly, neither **Sabokbar et al.** nor **Merck Co.** anticipates the present invention. Similarly, the combination of **Sabokbar et al.** and **Merck Co.** does not render the present invention obvious because the cited references taken together do not teach or suggest each and every limitation recited herein.

In view of the above remarks, Applicants respectfully request that the rejection of claims 77-117 and 122-125 under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) be withdrawn.

Conclusion

Applicants maintain that all the grounds of rejections raised in the February 21, 2006 Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

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No fee besides the FIVE HUNDRED AND TEN DOLLARS ($510.00) fee for the three-month extension of time for a small entity is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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